

### **Remarks**

The final Office Action dated December 19, 2007 has been reviewed and following remarks are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration of this application and timely allowance of the pending claims. Claims 1-23 are pending.

### **Rejections under 35 U.S.C. 103**

Claims 1-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Berger *et al.* (U.S. Patent No. 4,470,975) ("*Berger*") in view of Samejima *et al.* (EP 0077956) ("*Samejima*") and Thompson *et al.* (U.S. Patent No. 5,004,603) ("*Thompson*"). In particular, the Examiner asserts that it would have been obvious at the time of the invention to make a composition comprising a water absorbent polymer of *Berger* with an enteric coating of *Samejima* with the absorption properties of *Thompson* (Office Action at page 5). Applicants respectfully traverse the rejection.

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103 the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. See *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) ("the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so," (citing *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (US 2007))). "Subsumed within the Graham factors is a subsidiary requirement articulated by this court that where, as here, all claim limitations are found in a number of prior art references, the burden falls on the challenger of the patent to show by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007) citing *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360 (Fed. Cir. 2006). As such, a finding of obviousness at least requires that the all of the claim elements be taught or suggested in the cited art.

Applicants respectfully submit that the cited references do not provide for direct administration of a water absorbent polymer, that is capable of absorbing at least 10 times its weight in physiological saline, as an active agent to the intestinal tract for increasing the fluid in

the feces. The Examiner states that *Berger* provides for direct administration of a water absorbent polymer to the intestinal tract because it provides for oral administration of the water absorbent polymer, which would allegedly pass through the intestinal tract (Office Action at page 6). The term "directly delivered" as used by Applicants is intended to mean that the polymer is not directly exposed to the stomach prior to delivery to the GI tract (Specification at page 9, lines 12-15). Such direct delivery of the polymer is not provided in *Berger*. Further, *Samejima* does not provide for the defects in *Berger*. *Samejima* describes the delivery to the intestinal tract of enterically coated microcapsules that are used to deliver active core materials (*Samejima*, page 3, lines 11-16). Notably, the water-swellaable polymer of *Samejima* swells and causes the microcapsules to break open thus releasing an active agent in the intestinal tract (*Samejima*, page 4, lines 21- 40). Since the water-swellaable polymer in the enterically coated microcapsules of *Samejima* was not used as an active agent, had limited absorption capacity (e.g., 1.2 to 1.5 times its weight) and was used only as an aid for dispersing the active agent, a skilled artisan would not be motivated to directly deliver the water absorbent polymer of *Berger* as an active agent to arrive at the instantly claimed invention.

Moreover, *Thompson* fails to remedy the defects present in *Berger* and *Samejima*. *Thompson* describes feeding ammonium polyacrylate polymers to animals, rather than directly administering the polymer to the intestine, as in the present invention. The Examiner relies on *Thompson* for the teaching of a water absorbent polymer that is capable of absorbing at least 10 times its weight in physiological saline (Office Action at page 7). However, one of skill in the art would not be motivated to use the water absorbent polymer of *Thompson* with the disclosure of *Berger* because these references use water absorbent polymers for vastly different purposes. In *Berger* the water absorbent polymer is used to absorb water from the gastrointestinal tract, while in *Thompson* the water absorbent polymer is used to help a ruminant livestock absorb more nitrogen from their food (*Thompson*, Abstract).

For the above-mentioned reasons, neither of the *Berger*, *Samejima* or *Thompson* taken singly or in combination provide or suggest directly delivering to the intestinal tract a water absorbent polymer that is capable of absorbing at least 10 times its weight in physiological saline. Further, even if combined these references would not provide or suggest direct delivery of a water absorbent polymer to the gastrointestinal tract. Given that all of the elements in independent claim 1 (from which claims 2-23 depend) are neither taught nor suggested by *Berger* alone or together with *Samejima* and *Thompson*, the instant claims cannot be obvious.

Accordingly, Applicants respectfully request that the rejection of claims 1-23 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

Conclusion

Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. The Examiner is respectfully requested to telephone the undersigned if he can assist in any way in expediting prosecution of this application. The Commissioner is authorized to charge any underpayment of fees or credit any overpayment of fees to Deposit Account No. 02-1818 (order no. 119204-12) for any matter in connection with this response.

Respectfully submitted,  
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